K002312
Page 1 of 2

AUG 3 0 2000

VARIAN
medical systems

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Premarket Notification [510K] Summary as required by 21 CFR 807.92

Date Summary was prepared;
July 26, 2000

Submitter's Name:
Varian Medical Systems
3100 Hansen Way
Palo Alto, CA 94304

Contact Person:
Linda S. Nash
Corporate Director, Regulatory Affairs and Quality Assurance
Phone (650) 424-6990
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Device Name:
ProtonVision 7.0

Classification Name:
Medical Charged Particle Radiation Therapy Systems

Predicate Device:
ProtonVision 7.0, K000922

Product Description:

The Varian ProtonVision is a computer based device used for calculating and displaying prospective or verification treatment plans for particular patients undergoing a course of proton therapy. The system consists of a computer with graphics display and plotter output. As a SomaVision (K992751) option, ProtonVision provides the capabilities of diagnostic image analysis, contouring and segmentation. In addition to SomaVision, ProtonVision provides tools for proton energy range estimation and dose compensation, proton dose calculation and dosimetric plan review. ProtonVision integrates proton treatment planning with Varian Vision applications.

Intended Use:

The Varian ProtonVision device is a treatment planning system used for diagnostic image analysis, contouring & segmentation, proton energy range estimation and dose compensation, proton dose calculation and plan review.

Technological Characteristics:

See attached Specification Comparison Chart, Tab F

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 0 2000

Ms. Linda S. Nash
Corporate Director, Regulatory Affairs
and Quality Assurance
Varian Medical Systems
3100 Hansen Way M/S E-055
Palo Alto, CA 94304-1129

Re: K002312
Proton Vision 7.0.3 Radiation Therapy
Treatment Planning System
Dated: July 26, 2000
Received: July 31, 2000
21 CFR §892.5050/Procode: 90 MUJ

Dear Ms. Nash:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

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Indications For Use

510(k) Number: K 002312

Device Name: ProtonVision 7.0

Indications For Use:

The Varian ProtonVision device is used to plan proton radiation therapy treatments employing proton accelerators with energies from 70 to 235 MeV. ProtonVision will plan the 3D radiotherapy proton treatment approaches to rectangle and circular fields, and regular and irregular fields using customized blocking and compensators. ProtonVision includes also tools for treatment preparation (diagnostic image analysis, contouring & segmentation) and plan review.

As part of the Varis Vision System, ProtonVision integrates proton treatment planning in overall therapy process, while taking advantage of the Varian Vision database.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002312

Prescription Use ✓ OR Over-The-Counter Use___
(per 21 CFR 801.109)